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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,265	09/28/2000	Michael Bott	BMID9975US	8449
75	90 02/07/2003			
Kenneth J. Waite Roche Diagnostics Corporation 9115 Hague Road, Bldg. D			EXAMINER	
			PATTERSON, CHARLES L JR	
P.O. Box 50457 Indianapolis, IN 46250-0457			ART UNIT	PAPER NUMBER
			1652	17
			DATE MAILED: 02/07/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	09/672,265	BOTT ET AL.				
Office Action Summary	Examiner	Art Unit				
	Charles L. Patterson, Jr.	1652				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1) Responsive to communication(s) filed on 12 N	lovember 2002 .					
2a)⊠ This action is <b>FINAL</b> . 2b)□ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 16,17,19,20 and 24-30 is/are pending in the application.						
4a) Of the above claim(s) <u>27-30</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>16,17,19,20 and 24-26</u> is/are rejected	•					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers  OVE The energiation is chiested to by the Exeminer						
9)  The specification is objected to by the Examiner.  10)  The drawing(s) filed on is/are: a)  □ accepted or b)  ○ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)□ Some * c)□ None of:						
1.⊠ Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents		tion No				
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Notice of Informa	ry (PTO-413) Paper No(s) I Patent Application (PTO-152)				

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Applicant's election without traverse of claims 16-26 in Paper No. 13 is acknowledged. Claims 27-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 13.

It is noted that applicant ignored the PTO-948 and the attachment to it regarding submitting the correction within the time period set for the action, and therefore it is reiterated. Applicants may no longer hold in abeyance drawing corrections.

The disclosure is objected to because of the following informalities:

In the last sentence of page 7 it is stated that genes "homologous to

E. coli citX are shown by light grey shading. Figure 2 does not contain any
"light grey shading". Applicants did not address this objection in their
amendment so it is repeated.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, 19, 20, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the genes citC, citD, citE, citF, citX and cit G in that order transformed into E. coli, does not reasonably provide enablement for the instant claims. The specification does not enable any person skilled in the art to which it per-

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tains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant misstates the examiner's rejection. The specification teaches that when the genes citC, citD, citE, citF, citX and citG in that order are placed into an expression vector, the citC, citD, citE, citF and citG genes being obtained from Klebsiella pneumoniae and the citX obtained from E. coli, and this vector transformed into E. coli, an active citrate lyase was produced. Applicants state that the amended claims "are limited such that the plasmid contains the listed genes, and that at least four of the genes are from Klebsiella pneumoniae and the DNA fragment is obtainable from E. coli" with support being found throughout the specification". The examiner does not agree. After a re-reading of the instant specification it is maintained that there is nothing teaching that "at least four genes are derived from Klebsiella pneumoniae and that the order of the genes in the plasmid can be other than citC, citD, citE, citF, citX and cit G.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the ad-

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visory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr.

Primary Examiner Art Unit 1652

Patterson February 4, 2003